

## **REMARKS**

The Office action dated August 20, 2009 is acknowledged. Claims 1-24 are pending in the instant application. Claims 7-15, 18-20 and 23-24 have been rejected and claims 1-6, 16, 17, 21 and 22 have been withdrawn. By the present Office Action response, claims 7-15 and 18-20 have been amended for clarification purposes. Reconsideration is respectfully requested in light of the arguments and amendments made herein. No new matter has been added.

### **Rejection of claims 7-15, 18-20 and 23-24 under 35 U.S.C. 101**

The Examiner has rejected claims 7-15, 18-20 and 23-24 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101.

Claims 7-15 and 18-20 have been amended accordingly to recite methods for treating a schizophrenic psychosis which is connected with at least one of increased monoamine oxidase and decreased functionality of nicotinic acetylcholine receptors. Claims 23-24 are in a format setting forth the steps involved and so no further amendment is necessary. Withdrawal of this rejection is requested.

### **Rejection of claims 7-15, 18-20 and 23-24 under 35 U.S.C. 112**

The Examiner has rejected claims 7-15, 18-20 and 23-24 under 35 U.S.C. 112 for the use of deoxyepanine for treating schizophrenic psychosis, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process the Applicant is intending to encompass. The Examiner has treated claims 7-15 and 18-20 as a method for treating schizophrenic psychosis by administration of deoxyepanine,

in the form of a free base or in the form of an acid addition salt, or of a derivative of deoxypeganine as long as said derivative is simultaneously an inhibitor of acetylcholinesterase and of monoamine oxidase.

Claims 7-15 and 18-20 have been amended accordingly. Claims 23-24 are in a format setting forth the steps involved and so no further amendment is necessary.

Withdrawal of this rejection is requested.

**Rejection of claim 7 under 35 U.S.C. 102(b)**

Claim 7 has been rejected under 35 U.S.C. 102(b) as being anticipated by Vonin, et al. (Stvo Meditsina; Moscow, Russia; Vol. 91, No. 2 (Feb. 1991), pages 111-115). The Examiner states that the Vonin, et al. reference teaches the treatment of schizophrenic patients with deoxypeganine (Abstract; page 115).

The Applicants respectfully disagree with the Examiner's conclusion and submit that the present invention as defined in the present claims is patentably distinct from the invention disclosed in the prior art Vonin, et al. reference. In particular, claim 7 of the presently claimed invention is directed to the use of deoxypeganine or a derivative of deoxypeganine as long as the derivative is simultaneously an inhibitor of acetylcholine esterase and of monoamine oxidase for treating schizophrenic psychosis which is connected with at least one of increased monoamine oxidase activity and decreased functionality of nicotinic receptors. In this regard, the Examiner states that Vonin, et al. teach the treatment of schizophrenic patients with deoxypeganine. The Applicants respectfully disagree. Vonin, et al. do not teach each and every limitation of the presently claimed invention.

As noted above, the presently claimed invention is generally directed to the

treatment of schizophrenic psychosis. Vonin, et al. disclose the treatment of patients suffering from schizophrenia accompanied by well-defined apathoabulic symptoms. In particular, to carry out the clinical study of Vonin, et al., patients with pronounced apathoabulic symptoms were chosen. According to Vonin, et al., these patients do not show any signs of psychosis. Thus, Vonin, et al. do not describe the treatment of patients suffering from schizophrenic psychosis, but rather only the treatment of patients suffering from schizophrenia accompanied by well-defined apathoabulic symptoms.

In addition, the presently claimed invention is directed to the use of deoxypeganine, either in the form of a free base or in the form of an acid addition salt (claim 23). Vonin, et al. describe the use of a combination of an anticholinesterase agent, either galanthamine or deoxypeganine, with M-cholinolytic drug benactyzine. Thus, the Vonin, et al. reference also differs from the presently claimed invention in regards to the choice of active agents.

Moreover, the Vonin, et al. reference teaches that only two out of thirty patients received a combination of deoxypeganine and amizil. However, the Vonin, et al. reference does not describe that an effective treatment of apathoabulic symptoms of schizophrenia can be accomplished by the use of a combination of deoxypeganine and amizil. As the Vonin, et al. reference does not report any effect of the combination of deoxypeganine and amizil in the treatment of people affected with schizophrenia, it is submitted that there is no disclosure of a positive effect on the treatment of people affected with schizophrenia psychosis.

The presently claimed invention also differs from the Vonin, et al. reference in the type of schizophrenic psychosis which is treated. The presently claimed invention is in

particular directed to the treatment of schizophrenic psychosis which is connected with at least one of increased monoamine oxidase activity and decreased functionality of nicotinic acetylcholine receptors. However, there is no disclosure in the Vonin, et al. reference of this specific type of schizophrenic psychosis to be treated.

In conclusion, it is submitted that Vonin, et al. fail to teach each and every limitation of the present claims, and therefore fail to anticipate the present invention as set forth in the present claims. Withdrawal of this rejection is respectfully requested.

**Rejection of claims 8-15, 18-20 and 23-24 under 35 U.S.C. 103(a)**

Claims 8-15, 18-20 and 23-24 have been rejected as being unpatentable over Vonin, et al., as applied to claim 7, and in view of U.S. Publication No. 2004/0132751 (Opitz, et al.) The Examiner states that Vonin, et al. disclose the treatment of schizophrenic patients with deoxypeganine, but do not disclose a daily dose, the proportions of the active substance in a pharmaceutical or route of administration. The Examiner refers to Opitz, et al. for teaching the use of deoxypeganine for the treatment of disorders of CNS, including psychiatric symptoms and for teaching that deoxypeganine can be used in its free base form or as an acid addition salt, with preferred salt being deoxypeganine hydrochloride and hydrobromide. The Examiner also states that Opitz, et al. teach that deoxypeganine is administered in a pharmaceutical preparation which contains the agent in proportions of from 0.1 to 90% by weight calculated as free deoxypeganine and that the daily dose is in the range from 0.1 to 100 mg. The Examiner also states that it is taught that deoxypeganine can be administered orally, parenterally, as a depot medicament and transdermally. Lastly, the Examiner states that derivatives are structurally analogous to deoxypeganine and will have the same property of inhibiting

both acetylcholinesterase and monoamine oxidase, absent a showing of unexpected results. Thus, the Examiner thus concludes that the combination of teachings of Vonin, et al. and Opitz, et al. render the presently claimed invention obvious.

It is respectfully submitted that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants first respectfully disagree with the Examiner's position for at least the numerous deficiencies of Vonin, et al. set forth above. Optiz, et al. fail to make up for any of the deficiencies of Vonin, et al. Therefore, the combination of teachings of Vonin, et al. with Opitz, et al. fail to teach each and every limitation of the present claimed invention. Therefore, the Applicants respectfully request that this obviousness rejection be withdrawn.

### **Conclusion**

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the

foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicants strongly urge that the obviousness-type rejection and anticipation rejections be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

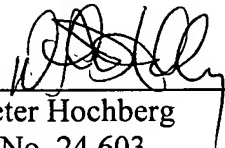
Respectfully submitted,

Date:

January 19, 2010

D. Peter Hochberg Co., L.P.A.  
1940 East 6<sup>th</sup> Street, 6<sup>th</sup> Floor  
Cleveland, OH 44114  
(216) 771-3800

By:

  
D. Peter Hochberg  
Reg. No. 24,603